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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,749	01/14/2002	Michael Vajdy	16464.003	5494

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EXAMINER

BROWN, TIMOTHY M

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

10/051,749

Applicant(s)

VAJDY ET AL.

Examiner

Timothy M. Brown

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-- Th MAILING DATE of this communication appears on th cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 6,7 and 22-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8-21,29 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Final Office Action is responsive to Applicants' amendment mailed October 29, 2004. Claims 1-30 are pending, of which claims 6, 7 and 22-28 have been withdrawn. Claims 1-5, 8-21, 29 and 30 are under examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 8-14, 16-20, 29 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Malone et al. (U.S. Pat. No. 6,110,898) ("Malone").

Applicants' invention is drawn to a method of generating a cellular immune response comprising administering, to the mucosa of a subject, an antigenic polynucleotide. The antigenic polynucleotide encodes an antigen from a sexually transmitted disease. The invention administers the polynucleotide using an alphavirus vector that may take the form of a replicon. The alphavirus vector further comprises a Sinbis virus and an HIV-1 antigen. According to the invention, the polynucleotide is introduced to the vaginal, rectal and nasal mucosal surfaces. The polynucleotide is delivered to antigen presenting dendritic cells.

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Malone anticipates Applicants' invention because it discloses a method of inducing a mucosal immune response wherein an antigenic polynucleotide is administered to the vaginal, nasal or rectal mucosal membranes of a subject (abstract, lines 2-4; col. 14, lines 64-66; col. 15, lines 57-62; and col. 17, lines 61-63). Malone's antigenic polynucleotide may be derived from a sexually transmitted virus such as HIV-1 (col. 20, lines 7-10 and 23-25). Malone further provides that the polynucleotide is delivered by an alphaviral vector such as Sinbis or Semliki Forest virus (col. 11, lines 39-41). Malone's alphaviral vector comprises a replicon (col. 2, line 66-col. 3, line 1).

Note that Malone inherently discloses presenting an antigenic polynucleotide to dendritic cells. This results because mucosal membranes are a natural environment for dendritic cells. Thus, by introducing an antigenic polynucleotide to a mucosal surface, Malone necessarily discloses presenting the antigenic polynucleotide to dendritic cells.

Malone also teaches eliciting an HLA class I or HLA class II response through inherency. This results because Malone administers the antigenic polynucleotide to a human (col. 15, line 52). Causing a human to express the antigenic polynucleotide would necessarily result in an HLA class I and HLA class II response. Malone therefore discloses an HLA class I or HLA class II response through inherency.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Malone in view of Parker et al. (U.S. Pat. No. 6,261,570) ("Parker").

As noted above, Malone teaches a method of generating a cellular immune response comprising administering an antigenic polynucleotide to the mucosa of a subject. Malone does not expressly teach "wherein said alphavirus vector comprises elements from two or more alphaviruses." However, Parker discloses vaccines directed against numerous alphavirus pathogens including Western Encephalitis virus, Eastern Encephalitis virus and Venezuelan Encephalitis virus (abstract, lines 1-4). Parker also discloses expressing antigens of other alphaviruses as chimeric alphaviruses for use as potential vaccines for humans (col. 5, lines 39-51). The knowledge generally available to the skilled artisan appreciates that an alphaviral vector may be modified with other antigenic sequences to achieve immunity against a desired pathogen. Therefore, at the time of Applicants' invention, it would have been obvious to one of ordinary skill in the art to modify Malone to include the teachings of Parker as this combination would provide a method for inducing mucosal immunity against a variety of alphaviral pathogens.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Malone in view of De Plaen et al. (U.S. Pat. No. 5,612,201) ("De Plaen").

Claim 21 is drawn to introducing a nucleic acid encoding either MHC-I or MHC-II into the target cells prior, or subsequent to, the administration of the antigenic polynucleotide. While Malone teaches the method of inducing mucosal immunity noted above, it does not expressly teach introducing either a MHC-I or MHC-II sequence as claimed. However, De Plaen teaches administering a MHC sequence to a target cell prior to transformation of the target cell. De Plaen explains that the advantage of this procedure is to enhance the immunoreactive response of the

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targeted cell (see col. 33, lines 6-19). Therefore, at the time of Applicants' invention, it would have been obvious to one of ordinary skill in the art, to modify Malone to include the teachings of De Plaen since this combination would improve the immunogenicity of Malone's method of mucosal immunization.

Response to Arguments

35 U.S.C. 102

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a cellular immune response) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants argue Malone fails to teach generating a cell-mediated immune response. The Examiner respectfully submits that Applicants' amendment does not require this limitation. As amended, the claims recite "generating a cellular immune response." A reasonable interpretation of "cellular immune response" reads on any antigen-mediated immune system activity that is carried out by a cell. Thus, Malone's production of IgG (see e.g. Fig. 1) necessarily involves a "cellular immune response" because IgG is produced by plasma cells in response to being activated by the recognition of an antigen. Accordingly, Malone teaches generating a cellular immune response as claimed.

35 U.S.C. 103

Applicants argue the combination of Malone and Parker et al. fail to teach an alphavirus vector that comprises an antigen that is heterologous to the vector. The Examiner respectfully

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submits Parker et al. meet this limitation. Parker et al. disclose a range of attenuated alphaviral vectors comprising various combinations of Western equine encephalitis (WEE) virus cDNAs. In particular, Parker et al. provide that their WEE vectors provide “a means for expressing antigens of *other alphaviruses* as chimeric alphaviruses” (col. 5, lines 38-41). Because Parker et al.’s alphaviral vector contains cDNA’s from other alphaviruses, and is disclosed as a being a “chimeric alphavirus,” Parker et al. teach a chimeric alphavirus vector as claimed.

Conclusion

The new grounds of rejection that were presented in the alternative in this Office Action were necessitated by Applicant's amendment. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy M. Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy M. Brown
Examiner
Art Unit 1648

tmb


JAMES HOUSEL 1/10/05
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